SEP 14 2009

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5.0 510(k) Summary

1. Sponsor

SpineFrontier, Inc.
500 Cummings Center
Suite 3500
Beverly, MA 01915

Primary Contact: John Sullivan
Telephone: 1- 978-232-3990

Date Prepared: May 29, 2009

2. Device Name and Classification:

Proprietary Name:	***Dorado™ Wide Intervertebral Body Cage, Dorado™ Wide IBC, Dorado™ Wide IBF***
Common/Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification Name:	Intervertebral Fusion Device With Bone Graft, Lumbar, (21 CFR 888.3080), Class II
Product Code:	MAX

3. Predicate Devices

K072289 – SpineFrontier Inc., Dorado Intervertebral Body Cage
P960025 – Saber Lumbar I/F Cage and Jaguar Lumbar I/F Cage

4. Device Description

The ***DORADO™ Wide Intervertebral Body Cage*** is a spinal intervertebral body cage intended for a posterior approach and uses autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. The system is comprised of devices of various fixed heights and footprints to fit the anatomical needs of a wide variety of patients. The device has raised contours on the superior and inferior surfaces that will resist implant expulsion.

5. Intended Use

The ***DORADO™ Wide Intervertebral Body Cage*** is a spinal intervertebral body cage intended for a posterior approach and uses autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolithesis at the involved level(s). The SpineFrontier ***DORADO™ Wide Intervertebral Body Cage*** is intended to be used with supplemental spinal fixation system(s) (Example: Posterior Pedicle Screw). Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six months of nonoperative treatment.

6. Technological Characteristics

The SpineFrontier ***Dorado™ Wide*** **Intervertebral Body Cage** was shown to be substantially equivalent to predicate devices through comparison of indications for use, function, operating principles, and materials.

7. Basis for Substantial Equivalence

The ***Dorado™ Wide*** **Intervertebral Body Cage** was evaluated in accordance with FDA Document, *Class II Special Controls, Guidance Document: Intervertebral Fusion Device, June 12, 2007*, and has been found to meet criteria defined in the guidance document; and has been demonstrated to be substantially equivalent to predicate devices in terms of indications for use, function, materials, and performance (mechanical testing). Clinical data was not required for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 14 2009

Spinefrontier, Inc.
% Mr. John Sullivan
Director of QA and Regulatory Compliance
500 Cummings Center, Suite 3500
Beverly, Massachusetts 01915

Re: K091638
Trade/Device Name: Dorado™ Wide Intervertebral Body Cage
Regulation Number: 21CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: September 1, 2009
Received: September 3, 2009

Dear Mr. Sullivan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krone

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if Known): _____

Indications For Use:

The ***DORADO™ Wide Intervertebral Body Cage*** is a spinal intervertebral body cage
intended for a posterior approach and uses autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolithesis at the involved level(s). The SpineFrontier ***DORADO™ Wide Intervertebral Body Cage*** is intended to be used with supplemental spinal fixation system(s) (Example: Posterior Pedicle Screw).

Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history or radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Prescription Use: X **AND/OR** **Over-The-Counter Use:** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 807 Subpart C)**

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091638